

REMARKS

Claims 73-86 are pending in the present application. The claims have been amended in the expectation that the amendments will place this application in condition for allowance. Applicants have limited the pending claims to method claims solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), 65 Fed. Reg. 54603 (September 8, 2000) without prejudice or disclaimer to the canceled subject matter. Applicants maintain the right to re-prosecute the canceled subject matter in a later filed divisional application. Non-elected subject matter has also been removed from the scope of the claims. The amendments do not introduce new matter within the meaning of 35 U.S.C. § 132. Accordingly, entry of the amendments is respectfully requested.

1. Rejection of Claims 1-11 under 35 U.S.C. § 112, 2d paragraph

The Official Action states that the rejection of claims 1-11 under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph is maintained. The subject

matter of claims 1-11 has been canceled, removing the present grounds for rejection.

**2. Rejection of Claims 1-11 under 35 U.S.C. § 112, 1st paragraph**

The Official Action states that claims 1-11 are rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph as containing new matter. Applicants thank the Examiner for her suggestion regarding the claims. The term "alkylenyl" has been removed from the pending claim, removing the present grounds for rejection.

**3. Rejection of Claims 1-4 under 35 U.S.C. § 102(b)**

The Official action states that the rejection of claims 1-4 under 35 U.S.C. § 102(b) as being anticipated by Henery-Logan, Andrew, or Dunkerton is maintained. The subject matter of claims 1-4 has been canceled, removing the present grounds for rejection.

**4. Rejection of Claims 1-5 under 35 U.S.C. § 103(a)**

The Official Action states that the rejection of claims 1-5 under 35 U.S.C. § 103(a) as being obvious over Henery-Logan or Andrew or Dunkerton has been maintained. The subject matter of claims 1-5 has been canceled, removing the present grounds for rejection.

**5. Rejection of Claims 1-11 and 14-25 for**

**Obviousness-Type Double Patenting**

The Official Action states that the rejection of claims 1-11 and 14-25 under the judicially created doctrine of obviousness-type

double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,801,187 (the '187 patent) is maintained. Applicants respectfully traverse this rejection.

The judicially-created doctrine of obviousness-type double patenting prohibits a party from obtaining an extension of exclusive rights through claims in a later patent that are not patentably distinct from claims in an earlier patent. See *Eli Lilly & Co. v. Barr Laboratories Inc.*, 55 USPQ2d 1609, 1617 (Fed. Cir. 2000); *In re Braat*, 19 USPQ2d 1289, 1291-92 (Fed. Cir. 1991); *In re Longi*, 225 USPQ 645, 648 (Fed. Cir. 1985). "The fundamental reason for the rule [of obviousness-type double patenting] is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." *Eli Lilly & Co. v. Barr Laboratories Inc.*, 55 USPQ2d 1609, 1617 (Fed. Cir. 2000) (quoting *In re Van Ornum*, 214 USPQ 761, 766 (C.C.P.A. 1982)).

In the present application, none of pending claims 73-86, if patented, would extend the right to exclude granted by claims 1-12 of the '187 patent. As stated previously, the '187 patent is directed solely to compounds having an ester attached at the 2-position of the central heterocyclic ring. Carboxylic acids and carboxylic acid isosteres are not included within the scope of protection of the claims of the '187 patent.

In contrast, the presently claimed invention is directed

solely to methods of treating a neurological disorder in an animal through the use of compounds having a carboxylic acid or carboxylic acid isostere attached at the 2-position of the central heterocyclic ring. Esters are not included within the scope of protection afforded by the present claims. In particular, the claims recite specific R<sub>2</sub> moieties for the compounds used in the claimed methods, none of which is an ester group. Accordingly, the presently claimed invention does not extend the right to exclude granted by the '187 patent.

Regarding the Examiner's citation of CA 122:31423 and CA 120:54750 as showing various isosteres of carboxylic acid, this does not impact the claimed invention. There is no motivation to combine either of these references with the '187 patent to arrive at the presently claimed invention.

Moltzen et al., *J. Med. Chem.*, 1994, 37, 4085-4099 (CA 120:54750) disclose compounds having a tetrazole or a triazole attached at the 3-position of a central heterocyclic ring. In contrast, both the present application and the '187 patent disclose compounds having substituents attached at the 2-position of a central heterocyclic ring. Moltzen et al. provide no teaching that the 3-position substituents would be equally effective as a substituent at the 2-position of the heterocyclic rings.

Additionally, Moltzen et al. teach the tetrazole and triazole

moieties as substituents on an unsaturated heterocyclic ring. In contrast, both the present application and the '187 patent teach substituents on a saturated heterocyclic ring. Accordingly, a person of ordinary skill in the art would have no motivation to combine the teachings of Moltzen et al. to arrive at the presently claimed invention.

Carroll et al., *J. Med. Chem.*, 1993, 36, 2886-2890 (CA 122:31423) disclose compounds having an oxadiazole attached to a central bridged heterocyclic ring. In contrast, both the present application and the '187 patent disclose compounds having substituents attached to a central non-bridged heterocyclic ring. Carroll et al. provide no teaching that the oxadiazole substituent would be equally effective attached to a non-bridged ring as it is attached to a bridged ring. Accordingly, a person of ordinary skill in the art would have no motivation to combine the teachings of Carroll et al. to arrive at the presently claimed invention.

The disclosures of Moltzen et al. and Carroll et al. represent an unobvious expansion of the teaching of the '187 patent. It would have been unexpected to a person of ordinary skill in the art to combine the teachings of these two secondary references with the '187 patent to arrive at the presently claimed invention. Nevertheless, applicants have amended the claims to remove tetrazole, triazole, and oxadiazole as possible substituents of the

central heterocyclic ring to speed prosecution of the instant application. In this regard, applicants respectfully point out to the Examiner that the claims recite specific R2 moieties for the compounds used in the claimed methods. Neither of the prior art references cited by the Examiner mention any of these specific R2 moieties. Accordingly, the prior art references cited by the Examiner do not teach or suggest all the limitations of the all of the claims.

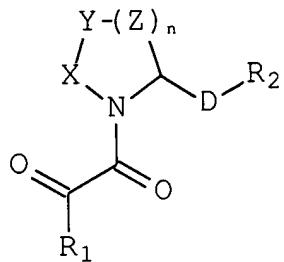
Regarding the Examiner's assertion that reference CA 67:10051 shows that the claimed compounds where "D is methylene, R2 is OR3 compounds, i.e. CH<sub>2</sub>OR<sub>3</sub> wherein R<sub>3</sub> is C<sub>1-6</sub> alkyl...is an bioisosteric replacement of the esters wherein the carbonyl is replace with a isostere moiety methylene", this is incorrect. In particular, CA 67:10051 states that "A substitution of the carbonyl group in procaine derivs. by S, O, CH<sub>2</sub>, NH, and SO<sub>2</sub> groups generally decreased their anesthetic effectiveness." (Emphasis added) Accordingly, this reference actually teaches away from the CH<sub>2</sub>OR<sub>3</sub> group as a bioisostere of its corresponding ester since a person of ordinary skill in the art would expect the ester to be more effective.

The Examiner has asserted that:

"D is bond R3 is COOR4 and R4 is C<sub>1-9</sub> alkyl, it is and ester and not proviso can be found that such ester is

excluded".

However, this does not impact the claimed invention. Applicants agree with the Examiner that D can possibly be a bond, R<sub>3</sub> can possibly be COOR<sub>4</sub>, and R<sub>4</sub> can possibly be C<sub>1</sub>-C<sub>9</sub> alkyl. However, the present invention is directed to methods of using compounds of the formula:



Please note that even when D, R<sub>3</sub>, and R<sub>4</sub> are defined as stated by the Examiner, it is not possible for the compounds used in the claimed methods to have an ester attached at the 2-position of the central heterocyclic ring since this would ignore the presence of the R<sub>2</sub> substituent. D can not possibly bond directly to R<sub>3</sub> in the compounds recited in the claims; rather, it is the carboxylic acid or carboxylic acid isostere of R<sub>2</sub> that is substituted with R<sub>3</sub>. Accordingly, it is not possible to modify the compounds used in the claimed methods to arrive at an ester as described by the Examiner.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claims 73-86.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections of pending claims 73-86 and allow all pending claims presented herein for reconsideration. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments.

Respectfully submitted,

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